



## A knowledgeable Notified Body with an expert team

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**Samantha Neilson,**  
Regulatory Affairs Manager,  
Smith & Nephew Medical Ltd

### **Smith & Nephew at a glance**

Smith & Nephew Medical Ltd are a global manufacturer offering a range of advanced wound care dressings; the range covers Class I through to Class III medical devices. These dressings provide clinical solutions for both acute and chronic wound types.

With a wide portfolio of wound care products, they take a pioneering approach to the design of products and services, and strive to secure wider access to new and innovative technologies for more customers.

Smith & Nephew places a high priority on the responsibility to act ethically and in compliance with the laws and regulations in the countries in which they operate. In addition, they believe being compliant helps them to provide better products and services for patients and Healthcare Professionals.

Smith & Nephew needs a Notified Body that understands their market and who responds to their challenges and product timings. By selecting BSI as its Notified Body, Smith & Nephew is able to meet their requirements, with the knowledge of a dedicated, expert team.

## Motivations to continue working with BSI:

### Notified Body status

Smith & Nephew have been working with BSI since the introduction of CE marking for medical devices in 1994. They are confident about working with BSI due to a large, dedicated team of knowledgeable experts providing certification and auditing services.

In an ever changing regulatory environment, BSI remains at the forefront of these changes, actively involved in the development of standards, directives and regulations.

Samantha Neilson, Regulatory Affairs Manager at Smith & Nephew Medical Ltd, says, "BSI are at the cutting edge of regulations and knowing about upcoming revisions; they also have a variety of different resources including webinars about upcoming changes which gives us more confidence in our Notified Body."

Smith & Nephew Advanced Wound Management designs, develops and manufactures a wide range of devices, including high risk advanced wound dressings e.g. device drug combinations. The high risk nature of these devices requires a high level of scrutiny by the Notified Body and Competent Authority. The Notified Body role requires confirmation of the safety and performance of the devices and verification of the effectiveness of the quality management system. "When we chose our Notified Body, it needed to be one that we could trust, had knowledge within our industry and one that was efficient in its processes... this is why we chose to work with BSI."

### Specialist scheme managers

BSI has specialist scheme managers who are the dedicated point of contact for all medical device certification requirements. These scheme managers guide manufacturers from first application for services right through to certification and beyond. For Smith & Nephew, they have been crucial for coordinating the necessary activities to support certification, and their role includes identification of appropriate regulatory paths and Notified Body resources required, determination of when Competent Authority involvement is needed. Upon completion of required audits, reviews and Competent Authority consultations, the scheme manager must review the outcomes to determine whether a recommendation for certification can be made. These scheme managers are key to Smith & Nephew in building confidence and trust between manufacturer and Notified Body and in ensuring the most efficient delivery of Notified Body services.

### Dedicated design dossier reviews\*

BSI offer a dedicated service for reviewing design dossiers, both on-site and off-site. Smith & Nephew have found that this is an excellent way of working in terms of having predictable approval timings for new products, as well as changes to existing products. It aids production planning, product launches and the initiation of subsequent global market registration activities..

"Dedicated design dossier reviews offer a vital opportunity to gain insight into the design dossier review process as a result of receiving direct feedback and questions from

the reviewers themselves. Ultimately, this has helped us educate the wider business functions on future projects, and when preparing future dossiers the process is more streamlined and saves us time," said Samantha.

*\*BSI's dedicated design dossier review services are subject to availability.*

### Training

BSI has a vast range of training courses covering current and relevant topics. Smith & Nephew recently benefited from a course held at their offices for a group of staff, focusing on clinical evidence requirements, which was delivered by BSI technical experts. "We found this to be an excellent way of learning up to the minute thinking and expectations."

**"BSI provides clients with a scheme manager who, from a regulatory perspective, is a central point of contact for managing these activities."**

**Samantha Neilson**, Regulatory Affairs Manager, Smith & Nephew Medical Ltd.

### Looking forward to further benefits:

The close working relationship between Smith & Nephew and BSI has been critical over the past 20 years. This will continue in the future as Smith & Nephew develop new products and work with BSI through the evolving regulatory framework, whilst benefiting from regular training and regulatory updates on topics.

## Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more about BSI services, please call or email us for an initial conversation

Call: **+44 345 080 9000**

Email: **eu.medicaldevices@bsigroup.com**

or visit: **bsigroup.com/medical**

**bsi.**

#### BSI Group America Inc.

12950 Worldgate Drive,  
Suite 800,  
Herndon,  
VA 20170  
USA

T: +1 800 862 4977/703 437 9000

F: +1 703 437 9001

E: us.medicaldevices@bsigroup.com

#### BSI Group - EMEA

Kitemark Court,  
Davy Avenue,  
Knowlhill,  
Milton Keynes MK5 8PP  
United Kingdom

T: +44 345 080 9000

F: +44 1908 814920

E: eu.medicaldevices@bsigroup.com

#### BSI Group Asia Pac

BSI Group - Hong Kong  
23rd Floor, Cambridge House  
TaiKoo Place,  
979 King's Road,  
Island East, Hong Kong

T: +852 3149 3320

F: +852 2743 8727

E: hk@bsigroup.com

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